

BENZALKONIUM CHLORIDE- antibacterial hand soap refill liquid
Brands International Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Antibacterial Hand Soap Refill

Benzalkonium Chloride - 0.13%

Purpose - Antibacterial

Use for handwashing to decrease bacteria on the skin

Warning - For external use only - hands only

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation or redness develops
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Wet Hands
- Apply palmful to hands
- scrub thoroughly
- rinse thoroughly

Inactive Ingredients: Water (Aqua), Sodium Laureth Sulfate, Cocamidopropyl Betaine, Sodium Chloride, Citric Acid, Glycerin, Fragrance (Parfum), Tetrasodium EDTA, Methylchloroisoithiazolinone, Methylisothiazolinone, Yellow# 5 (CI 19140), Red# 4 (CI 14700)

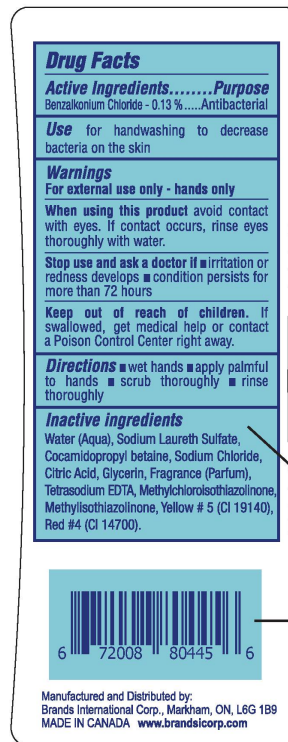
Visibly Clean Antibacterial Hand Soap Refill

WHITE FILM
5.75" X 2.25"



4 colors + Reflex Blue

CLEAR FILM
5.75" X 2.25"



Back label: 2 colors
White and Reflex blue

white box under UPC
and Drug Facts box

BENZALKONIUM CHLORIDE

antibacterial hand soap refill liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50 157-206
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
DITETRACYCLINE TETRASODIUM EDETATE (UNII: WX0A0IT7K5)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	

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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50157-206-25	739 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/03/2016	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	10/03/2016	

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Labeler - Brands International Corporation (243748238)

Establishment

Name	Address	ID/FEI	Business Operations
Brands International Corporation		243748238	manufacture(50157-206)

Revised: 10/2016

Brands International Corporation